Small Business Statement

A regulatory flexibility analysis pursuant to R.S. 49:965.6 has been conducted. It has been determined that the promulgation of this Rule will not have an adverse impact on small business.

Public Comments

Interested persons may submit written comments to Hugh Eley, Office of Aging and Adult Services, P.O. Box 2031, Baton Rouge, LA 70821-2031. He is responsible for responding to inquiries regarding this proposed Rule. The deadline for the receipt of all written comments is 4:30 p.m. on the next business day following the public hearing.

Public Hearing

A public hearing on this proposed Rule is scheduled for October 30, 2013 at 1 p.m. in Room 118, Bienville Building, 628 North Fourth Street, Baton Rouge, LA. At that time all interested individuals will be afforded an opportunity to submit data, views or arguments either orally or in writing.

Kathy Kliebert
Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Traumatic Head and Spinal Cord Injury Trust Fund Program

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

This rule proposes to repeal the current Department of Children and Family (DCFS) rule governing the Traumatic Head and Spinal Cord Injury Trust Fund Program, Louisiana Administrative Code (LAC) Title 67, Part VII, Section 1901-1927. Per statute, the Department of Health and Hospitals (DHH), Office of Aging and Adult Services (OAAS) is now responsible for administration of the Louisiana Traumatic Head and Spinal Cord Injury Trust Fund under the promulgation of LAC Title 48, Part I, Section 1901-1925. The Traumatic Head and Spinal Cord Injury Trust Fund Advisory Board is also placed within DHH.

This proposed rule change does not affect current services offered through the Traumatic Head and Spinal Cord Injury Trust Fund Program and therefore are not anticipated to result in any additional savings or costs, other than the cost of promulgation of the rule in the amount of $2,050 (SGF) in FY 13-14. This cost is routinely included in the agency's annual operating budget.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

There is no known effect on revenue collections of state or local governmental units.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

There is no known cost and/or economic benefit to directly affected persons or non-governmental groups.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This proposed rule is not anticipated to have any effect on competition and employment.

Hugh Eley
Assistant Secretary
1309#041

John D. Carpenter
Legislative Fiscal Officer
Legislative Fiscal Office

NOTICE OF INTENT

Department of Health and Hospitals
Office of the Secretary

Health Care Data Reporting (LAC 48:I.13101-13123)

The Department of Health and Hospitals, Office of the Secretary proposes to repeal LAC 48:V.Chapter 151 governing State Center for Health Statistics in its entirety and adopt LAC 48:I.Chapter 131 as authorized by R.S. 40:1300.111 et seq. This proposed Rule is promulgated under the authority of R.S. 40:1300.112(10) and in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq., as amended.

This rulemaking provides procedures and guidelines for the reporting of statewide health care data and the protection of the confidentiality of certain data elements in order to better understand patterns and trends in the availability, use, and charges of health care services, and the underlying patterns of disease which necessitate these services in the state. The department solicited feedback and collaboration from health care facilities and related professional associations in advance of the rulemaking process. The department conducted meetings, listening sessions in Monroe, Shreveport, Lake Charles, Lafayette, Marrero, and Baton Rouge, as well as hosted webinars between the months of April and August 2013 in an effort to receive input from participants and incorporate that feedback toward the completion of this proposed Rule.

Title 48
PUBLIC HEALTH – GENERAL
Part I. General Administration
Subpart 5. Health Planning
Chapter 131. Health Care Data Reporting
§13101. Purpose

A. Louisiana R.S. 40:1300.111 et seq. assigns to the Department of Health and Hospitals the responsibility for the collection and dissemination of health care data. The legislative action was based upon a finding that, as a consequence of rising health care costs, the shortage of health professionals and health care services in many areas of the state, and the concerns expressed by consumers, health care providers, third-party payers, and others involved with making informed decisions regarding health care services, treatment, and coverage, there is a need to have access to provider specific health care cost, quality, and outcome data on health care facilities, health care providers, and health plans as well as continued access to global patterns and trends in the availability, use, and charges for health care services and the associated health circumstances. The statute requires that all state agencies and health professional licensing, certification, or registration boards and commissions, which collect, maintain, or distribute health data, shall provide the information necessary to carry out the purpose of this law. In accordance with the statute, the collection of health care data is to be accomplished in collaboration with health care purchasers, hospitals and other service providers, consumer and patient advocacy groups, quality improvement and health information technology groups, physicians, and any other pertinent

individuals or groups comprising a health data panel appointed by the Secretary of the Department of Health and Hospitals. In addition, all health care providers licensed by the state, including but not limited to hospitals, outpatient surgical facilities, and outpatient clinical facilities, shall submit information in the manner and form prescribed in these regulations. It is the purpose of these regulations to provide directions for the required collection, submittal, management, and dissemination of health care data and to provide for the confidentiality of the data.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1300.112(10).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 39:

§13103. Definitions

A. For the purposes of these regulations, the following words and phrases, when used herein, shall be construed as listed below.

Act 537—Act 537 of the 2008 Regular Legislative Session, which amended and reenacted LA R.S. 40: 1300.111 et seq.

Aggregate Data Set—an array of counts of patient level records, or of totals of patient level record quantities (example: total charges), classified by data categories (example: "year of discharge"). Aggregate data sets may be used to present health data usefully, yet in a manner which can minimize potential for identification of confidential information.

Ambulatory Surgery Information—all billing, medical, and personal information describing a patient, the services received, and charges billed, associated with a single ambulatory-surgery procedure, according to the most current institutional-claim standards established by the National Uniform Billing Committee (NUBC) and the American National Standards Institute, Accredited Standards Committee (ANSI/ASC) X12.

Ambulatory Surgery (Data) Record—the structured document, in electronic form, of all the data for a single ambulatory-surgery procedure, or the data content of that document, according to the most current institutional-claim standards established by NUBC and ANSI/ASC X12. This often will include more than one data record.

Ambulatory Surgical Center—

a. an establishment, which is subject to licensure as an ambulatory surgical center by the department, with an organized medical staff of physicians, with permanent facilities that are equipped and operated primarily for the purpose of performing surgical procedures, with continuous physician services and registered professional nursing services available whenever a patient is in the facility, which does not provide services or other accommodations for patients to stay overnight, and which offers the following services whenever a patient is in the center:

i. drug services as needed for medical operations and procedures performed;

ii. provisions for physical and emotional well-being of patients;

iii. provision of emergency services;

iv. organized administrative structure;

v. administrative, statistical and medical records;

b. for the purposes of this rule, *ambulatory surgical center* also includes hospital-based facilities which perform ambulatory-surgery procedures.

Confidential Information—that information defined as confidential in this rule including, but not limited to:

a. employer identifiers, facility identifiers, patient or insured identifiers, payer identifiers, or physician or other service provider identifiers;

b. information identified by the identifiers;

c. combinations of data categories derived from part or all of the database information that would identify or tend to identify an employer, facility, patient or insured person, payor, or physician or other service provider;

d. *protected health information* as defined in the HIPAA Privacy Rule; and

e. information identified by combinations of these data categories.

Database—a structured repository of data, consisting of one or more related structured data tables.

Data Category—one of the typically (though not necessarily) non-unique data values of a data element, or to equivalent labels for these values. For example, the data categories of the data element years may be three in number: "12," "13," and "14," and may be labeled "2012," "2013," and "2014," whereas the data categories of the data element patient birth date may have thousands of possible values, some of which are probably uniquely associated with exactly one person.

Data Element—a logical field of a data record or a column of a data table, and includes both the named data elements in the Department's *Louisiana Health Care Data Specifications Manual*, and any other data elements obtained or created by analytic or synthetic methods. Examples: discharge year, age group, sex, or disease group.

Data Record—the row of a data table, or the set of related rows from related tables in a database.

Data Set—a structured subset of data from a database.

Department or *DHH*—the Louisiana Department of Health and Hospitals.

De-Identified Information—patient level data which have been de-identified in accordance with the requirements of the HIPAA Privacy Rule.

Emergency Services—services that are usually and customarily available at a licensed hospital and that must be provided immediately to stabilize a medical condition which, if not stabilized, could reasonably be expected to result in the loss of the person's life, serious permanent disfigurement or loss or impairment of the function of a bodily member or organ, or which is necessary to provide for the care of a woman in active labor if the hospital is so equipped and, if the hospital is not so equipped, to provide necessary treatment to allow the woman to travel to a more appropriate facility without undue risk of serious harm. For the purposes of this rule, such services are provided to a patient for a period of less than twenty-four consecutive hours and do not result in admission to a hospital as an inpatient.

Employer Identifier—employer name, employer location/address excluding the first three digits of the ZIP code, or other information that identifies an employer.

Facility Identifier—provider name, provider telephone number, provider FAX number, federal tax number or EIN, federal tax sub ID, Medicare provider number, national provider identifier, mailing address excluding the first three digits of the ZIP code, or other information that identifies a facility.

HIPAA Privacy Rule—federal regulations found at 42 CFR Part 160 and Part 164, Subparts A and E, promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health (HITECH) Act, which regulate the use and disclosure of protected health information held by "covered entities", including DHH.

Health Care Facility or *Facility*—a facility subject to licensure by the department as either a hospital or an ambulatory surgical center.

Hospital—any institution, place, building or agency, public or private, whether for profit or not-for-profit, which is subject to licensure as a hospital by the department, with facilities for the diagnosis, treatment, or care of persons who are suffering from illness, injury, infirmity, or deformity or other physical condition for which obstetrical, medical, or surgical services would be available and appropriate and which operates or is affiliated with facilities for the overnight care, observation, or recovery of those persons. The term *hospital* does not include the following:

a. physicians' offices or clinics where patients are not regularly kept as bed patients for 24 hours or more;

b. nursing homes as defined by and regulated under the provisions of R.S. 40:2009.1 through R.S. 40:2009.12;

c. persons, schools, institutions or organizations engaged in the care and treatment of mentally retarded children and which are required to be licensed by the provisions of R.S. 28:562 through R.S. 28:566;

d. hospitalization or care facilities maintained by the state at any of its penal and correctional institutions provided that nothing herein contained shall prevent a penal or correctional institution from applying for licensure of its hospitalization or care facility;

e. hospitalization or care facilities maintained by the federal government or agencies thereof;

f. hospitalization or care facilities maintained by any university or college provided that nothing herein contained shall prevent any college or university from applying for licensure of its hospitalization or care facility;

g. any other entity licensed for the diagnosis, treatment, or care of persons admitted for overnight stay.

Hospital Discharge Information—all billing, medical, and personal information describing a patient, the services received, and charges billed, associated with a single inpatient hospital stay or emergency department visit, according to the most current institutional-claim standards established by the National Uniform Billing Committee (NUBC) and the American National Standards Institute, Accredited Standards Committee (ANSI/ASC) X12.

Hospital Discharge (Data) Record—the structured document, in electronic form, of all the data for a single hospital stay or emergency-department visit, or the data content of that document, according to the most current institutional-claim standards established by NUBC and ANSI/ASC X12. This often will include more than one data record.

Hospital Stay or *Inpatient Hospital Stay*—the period, activities, events, and conditions associated with a patient, from the time of admission to a hospital, to the time of discharge from that hospital. Facilities licensed as hospitals and having different provider numbers are, for the purpose of this definition, distinct hospitals having discrete hospital stays and hospital discharges. In addition, for the purposes of this rule, a hospital stay lasts at least 24 consecutive hours.

Intermediary—a data processing agent of a hospital or ambulatory surgical center, who is contracted or employed by that hospital or ambulatory surgical center to relay their health care records to the department in compliance with these rules.

Manual—the *Louisiana Health Care Data Specifications Manual.*

Patient or *Insured Identifier*—patient name, insured's name, patient address or insured's address, patient control number, Social Security Number, medical record number, health insurance claim identification number, or any other identifier that must be removed in order to de-identify the information in accordance with the requirements of the HIPAA Privacy Rule.

Patient Level Data—the non-aggregate, one logical record per encounter, form of data submitted by hospitals or ambulatory surgical centers which includes part or all of the submitted data elements or recoded data derived from submitted data elements. This term refers to both the *raw* patient level data in the form in which it is submitted, and the cleaned patient level data which may have had error checking or edits applied or which may have been separated into the specifically named patient or insured identifier data elements and the remaining data elements. Patient level data may include all or part of the health care data record.

Payer Identifier—the payer name, payer identification, insured group name, insurance group number, or other information that identifies a payer.

Physician and Other Service Provider Identifier—attending physician name, attending physician number, operating physician name, operating physician number, other physician name, other physician number, or other information that identifies a physician or other service provider.

Publish—to make any health care information available in paper or electronic form to persons who are not department staff authorized to use that information.

Release—a conditional distribution of health care information for purposes authorized by this rule. The release may be conditioned upon the payment of a reasonable charge to compensate the department for the time and expense it incurs in providing copies of the information, in accordance with such statutes and rules regarding copying charges for health care records and public records as may be applicable.

Research—systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Secure Information—that information which is not subject to release by the department pursuant to this rule, and will not be released for any purpose. Secure information includes patient and insured identifiers.

Submit (with respect to a submission date, and data, reports, surveys, statements or documents required to be submitted to the department)—to deliver, or to cause to be delivered, to the department, in the form and format specified, by the close of business on the prescribed date.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1300.112(10).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 39:

§13105. Confidentiality

A. Act 537 provides for the strictest confidentiality of health care data and severe penalties for violation of the Act. To effectively govern this provision, the Act mandates that the department ensure confidentiality of patients by enforcing appropriate rules and regulations at least as stringent as the HIPAA Privacy Rule.

B. After editing and compilation of data submitted under this rule, DHH shall separate all patient and insured identifiers from the rest of the file. Redundant methods shall be employed to assure physical security, media security, transmission security, logical security, secure authorized access, and backup of all secure or confidential information. The collection, editing, compilation, storage, analysis, and dissemination of reports or data shall be done in a manner that protects publication of information that identifies or tends to identify an individual patient.

C. Patient level data and electronic forms of data collected and furnished for DHH shall not be available for public inspection.

D. Data may be used as described in §§13107 and 13109 below.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1300.112(10).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 39:

§13107. Use of Health Care Records by DHH

A. Patient level data (raw or cleaned) may be released by DHH to the data provider that submitted those particular data.

B. The department may use patient level data in fulfilling its public health mission and for purposes of program administration. The department will establish procedures for secure use of the data by DHH staff in accordance with the confidentiality provisions of Act 537 and the HIPAA Privacy Rule.

C. The department may release patient level data for use in research, in accordance with the provisions of §13109 of this rule.

D. Aggregate and De-Identified Information

1. In accordance with the provisions of Act 537 concerning the need of consumers to make informed decisions regarding health care services, treatment, and coverage, the department may develop and publish aggregate data reports and aggregate data, as resources permit, that do not disclose *confidential information* as defined in §13103 of this rule. The aggregate data reports and aggregate data shall be public information and may be distributed electronically as determined by DHH including, but not limited to, Internet publications.

2. The department may also release aggregate or de-identified data to parties outside DHH on request, as resources permit. Such data may be released when they do not disclose confidential information, as defined in §13103 of this rule. The data request should be made to DHH and may include:

a. rationale for the study or data use;

b. a summary of the project or study plan, including a definition of, and justification for the particular fields and records necessary for the project or study;

c. signed agreement for use of data affirming that data will be used only for the purpose stated in the request, and that no attempts will be made to combine data provided for this request with other data provided from a previous request or another source, or attempt to identify confidential information.

d. affirmation that a copy of any publication resulting from the use of the records shall be provided to the department;

e. a signed agreement to indemnify and hold the state, DHH, its employees, and the original providers of the patient level data harmless from any liability arising out of the authorized or unauthorized use of the data.

E. DHH Reports Containing Identifiers

1. The department may publish health care data reports with employer, facility, payer and/or physician and/or other health care provider identifiers. The criteria for release of such reports shall include, but are not limited to:

a. the report content and design reflect that the proposal is in the best interest of public health;

b. the reports reflect the use of accepted methods of data analysis;

c. the investigators/researchers are deemed qualified based on their past research, employment, and education;

d. provisions to protect the confidentiality of the patient identifiers comply with §13109 of this rule.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1300.112(10).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 39:

§13109. Use of Health Care Records in Research

A. Notwithstanding any other provision of this rule, non-aggregate (patient level) data may be disclosed for research purposes, but only under the following circumstances:

1. If the information sought to be used for research qualifies as a "limited data set" as defined in the HIPAA Privacy Rule, it may be released pursuant to a "data use agreement" that meets the specifications of the HIPAA Privacy Rule.

2. If the information sought to be used for research does not qualify as a "limited data set" as defined in the HIPAA Privacy Rule, it may be released only after approval has been given by the DHH Institutional Review Board pursuant to the policies and procedures contained in 45 CFR Part 46 and LAC 48:I.Chapter 25, Departmental Research (as promulgated in *Louisiana Register*, Vol. 24, No. 3, pp. 449-454, March 1998, or as it may be subsequently amended).

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1300.112(10).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 39:

§13111. Health Care Data Submittal—General

A. Data Reporting Source. All facilities operated and licensed as a hospital or ambulatory surgical center in the state of Louisiana by the department will report health care

data to the department for each patient admitted for inpatient services, emergency services, and/or ambulatory-surgery procedures depending on the types of health care services each licensed facility provides as defined by law. A failure to report may result in action by the licensing authority in accordance with R.S. 40:1300.114 E.

B. Reporting Responsibilities

1. The single billing health care data record must be submitted for the reporting period within which the discharge occurs. If a claim will not be submitted to a provider or carrier for collection (e.g., charitable service), a health care data record must still be submitted to DHH, with the normal and customary charges, as if the claim was being submitted.

2. Multiple Encounters. For a patient with multiple encounters, submit one health care data record for each encounter.

3. Multiple Billing Claims. For a patient with multiple billing claims, the facility should submit all data related to a discharge in one of two ways:

a. consolidate the multiple billings into one health care data record for submittal for the reporting period within which the discharge occurs; or

b. submit each interim billing claim for the reporting period in which the claim is generated.

4. A hospital or ambulatory surgical center may submit health care data directly to DHH, or may designate a third-party intermediary, such as a commercial data clearinghouse. Use of an intermediary does not relieve the health care facility from its reporting responsibility. In order to facilitate communication and problem solving, each facility should designate a contact person and a backup for the contact person. The facility will provide the names, telephone numbers, mailing and electronic-mail addresses, and job titles of the persons assigned this responsibility to DHH on forms provided by the department itself.

C. Confidentiality of Data. Act 537 provides for the strictest confidentiality of data and severe penalties for the violation of the Act. To effectively govern this provision, the Act mandates that DHH ensure confidentiality of patients by enforcing appropriate rules and regulations at least as stringent as the HIPAA Privacy Rule. Any information collected from hospitals or ambulatory surgical centers that identifies a patient or person under whom the patient is insured cannot be released. In addition, physician, facility, payer, or employer identifiers cannot be released without DHH approval. The department needs patient-specific information to complete analyses and will take every prudent action to ensure the confidentiality and security of the data submitted in accordance with state and federal law. Procedures include, but are not limited to, physical security and monitoring, separation of personal identifiers from the analytical file, access to the files by authorized personnel only, passwords, and encryption. Not all measures taken are documented in this rule to further protect the data.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1300.112(10).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 39:

§13113. Health Care Data Submittal—Schedules

A. Each licensed Louisiana hospital which collects inpatient discharge information, as set forth in this rule, shall submit inpatient hospital discharge records to the department in a manner that complies with the provisions of the guidelines here included for all hospital discharges occurring on or after January 1, 2014.

B. Each licensed Louisiana hospital which collects emergency-services information, as set forth in this rule, shall submit emergency-services records to DHH in a manner that complies with the provisions of the guidelines here included for all emergency services provided on or after January 1, 2015.

C. Each licensed Louisiana hospital-based or non-hospital-based ambulatory surgical center which collects ambulatory surgery information, as set forth in this rule, shall submit ambulatory surgery records to DHH in a manner that complies with the provisions of the guidelines here included for all ambulatory surgery procedures performed on or after January 1, 2016.

D. Submittal Schedules. Hospitals and ambulatory surgical centers (or either facilities' representatives) will generate and submit their health care data to the department according to schedules specified in the *Louisiana Health Care Data Specifications Manual*.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1300.112(10).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 39:

§13115. Health Care Data Submittal—Use of Data Processing Intermediaries

A. Third-party intermediaries may be utilized by hospitals and ambulatory surgical centers for the delivery of data to the department. Intermediaries must be registered with DHH on registration forms provided by the department itself. Additions and deletions to the intermediary's list of facilities represented must be submitted at least 10 days prior to the submittal schedule reporting due date.

B. Hospitals and ambulatory surgical centers shall notify the department by January 1 of each year if they plan to submit the required data to the department through a third-party intermediary that is registered with the department. Hospitals and ambulatory surgical centers selecting this option are responsible for ensuring that the submitted data conform to specifications contained in the *Louisiana Health Care Data Specifications Manual*. These specifications include, but are not limited to, the format, timeliness, and quality criteria of completeness, validity, and consistency outlined in the manual. The third-party intermediary is responsible to the hospital or ambulatory surgical center for ensuring that the data are submitted to the department in conformance with specifications contained in the manual.

C. The following additional requirements and information apply to intermediaries delivering data to DHH.

1. Data may be delivered in any number of submittals (i.e., one per facility, several facilities combined, or all facilities combined in one submittal), but the minimum unit of data submittal is all records from one facility per submittal time period.

2. Data may be submitted in any approved data format declared at the time of registration.

3. Data may be submitted using any approved transmittal process declared at the time of registration.

4. The intermediary must submit data for three or more facilities.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1300.112(10).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 39:

§13117. Health Care Data Submittal—Extensions and Waivers

A. All hospitals and ambulatory surgical centers will submit discharge data in a form consistent with the requirements unless an extension or waiver has been granted. Extensions may be granted when the facility documents that unforeseen difficulties, such as technical problems, prevent compliance. Waivers may be granted when the facility documents the need for data format changes before it can begin collecting and submitting specific data elements. Requests for extensions or waivers shall be in writing and directed to DHH.

1. Extension of Time for Data Submittal

a. Any facility which determines it temporarily will be unable to comply with a data submittal date or with data submittal time lines established in a previously submitted plan of correction may apply to the department for an extension. An application for extension shall be submitted at least 15 working days prior to the data submission deadline. The application for extension shall include specific reasons why the facility cannot comply with the rule in the required time frame, a specific plan sufficient to correct the problem, and the proposed data submission date.

b. The department shall act upon an application for extension of time within 10 working days of receiving the written request. Failure of the department to act on the application shall be deemed as a grant of the extension.

c. Following review of an extension application, the department shall notify the applicant, in writing, of the decision to approve or disapprove the application or modifications required to secure approval of the application. If DHH disapproves an application, it will include in its written notification a statement of the reasons for its decision. Also in the event of disapproval, DHH shall not accept requests for reconsideration as the department's decision shall be considered final.

d. Failure of the facility to submit an acceptable plan or to follow an accepted plan shall be considered continued and substantial noncompliance with this rule unless determined otherwise by DHH.

2. Waivers of Data Requirements

a. Any facility which determines it will be unable to comply with any of the provisions of this rule or with the provisions of a previously submitted plan of correction, for submission of particular data elements of the required format, quality, or completeness for specific discharge periods, may apply to the department for a waiver. A data element-based waiver may be granted for the submission of specific data elements for specific durations and does not, in this case, relieve the facility of the obligation to submit other required data elements in a timely manner. A general waiver may also be granted for compliance with the required data format. An application for waiver shall be submitted at least 30 working days prior to the data submission deadline on a form provided by the department. The application for waiver shall include specific reasons why the facility cannot comply with the rule, a specific plan sufficient to correct the problem(s), and the earliest date(s) when the facility will be compliant. Waivers will be granted upon determination of a satisfactory application during the first year, and as necessary thereafter.

b. The department shall act upon an application for waiver within 20 days of receiving the written request. Failure of the department to act on the application shall be deemed as a grant of the waiver.

c. Following review of a waiver application, the department shall notify the applicant, in writing, of the decision to approve or disapprove the application or modifications required to secure approval of the application. If DHH disapproves an application, it will include in its written notification a statement of the reasons for its decision. Also in the event of disapproval, DHH shall not accept requests for reconsideration as the department's decision shall be considered final.

d. Failure of the facility to submit an acceptable plan or to follow an accepted plan shall be considered continued and substantial noncompliance with this rule unless determined otherwise by DHH.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1300.112(10).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 39:

§13119. Health Care Data Submittal—Data Errors and Certification

A. Health care facilities will review their respective data records prior to submittal for accuracy and completeness. Correction of invalid records and validation of aggregate tabulation are the responsibility of the facility. All facilities will certify the data submitted for each reporting period in a manner specified by the Department of Health and Hospitals.

1. Error Correction

a. The facility is responsible for submitting accurate and complete data in one of the specified formats. The department, in turn, may identify errors for facility review, comment, and correction when applicable. The records with errors will be identified in a simplified format providing record identification and an indication or explanation of the error. The error report will be sent by electronic mail to the attention of the individual designated to receive the correspondence at the facility.

b. In the event 5 percent or more of the records per facility in a submittal period are in error, the submittal for that facility will be rejected. A record is in error when at least one required data element is missing or in error (excepting those elements for which a waiver has been granted). Notification of the rejection will accompany the error report and will be sent by electronic mail to the attention to the individual designated to receive the correspondence at the facility.

c. After the submittal has been corrected, the submittal is to be resubmitted, in its entirety and original format, to the department within the time frame specified in the manual. This correction cycle may repeat.

2. Certification and Review

a. Following receipt of a data submittal and completion of any needed error correction, the department will send the facility-designated contact a health care data summary report containing the total number of records received for the reporting period, by encounter, and by payer class for each facility.

b. The facility-designated responsible contact will validate, in writing, the accuracy of the health care data summary report and verify that the data sent were complete for that reporting period. Regardless of any waiver granted, the facility will provide an estimate of the number of any unreported encounters for the reporting period. The signed validation will be returned to DHH within 10 working days.

3. Noncompliance

a. Upon written notification of noncompliance from the department, the chief executive officer of the delinquent facility shall have 10 working days following receipt of the written notification of noncompliance to provide the department with a written plan for correcting the deficiency. The plan of correction shall include specific reasons why the facility cannot comply with the rule in the required time frame, a specific plan sufficient to correct the problem, and the proposed data submission date.

b. Failure of the facility to submit an acceptable plan or to follow an accepted plan shall be considered continued and substantial noncompliance with this rule unless determined otherwise by DHH.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1300.112(10).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 39:

§13121. Health Care Data Submittal—Specifications

A. Health care facilities shall submit data by electronic media as determined by DHH. Data submittals not in compliance with transmittal or format specifications will be rejected unless approval is obtained prior to the scheduled due date from the department. Data-submittal specification updates will be added to the *Louisiana Health Care Data Specifications Manual* and posted on the DHH Web page.

1. Transfer. Data submittal standards shall require the use of electronic transfer of database files (structure to be provided by DHH) via telecommunications. Editing of data prior to submittal is encouraged and assistance from DHH will be provided.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1300.112(10).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 39:

§13123. Health Care Data Submittal—Data Elements

A. The department shall make available to health care facilities a *Louisiana Health Care Data Specifications Manual* listing and defining the required and conditionally required data elements. Submission of any other data elements is optional; facilities do not need to suppress or strip other elements appearing in their claim files. All elements submitted will be treated confidentially in accordance with state and federal law.

1. Required Data Elements. If a facility is currently or temporarily unable to provide any of the data listed in the manual, the facility must apply for a waiver or extension, as detailed in §13117 of this rule.

2. Revisions to the Manual

a. The department shall notify health care facilities of revisions and/or corrections to the *Louisiana Health Care Data Specifications Manual* according to the National Uniform Billing Committee's (NUBC's) and American National Standards Institute, Accredited Standards Committee (ANSI/ASC) X12's most current implementation schedules for data-specification or electronic-data interchange (EDI) changes. In turn, facilities shall comply with data-specification and EDI requirements according to the most current version of the manual.

b. The DHH Health Data Panel shall review any new data elements and submit these to the secretary of the department with recommendations.

c. If state or federal law mandates immediate changes to either data specifications or electronic-data interchanges, Subparagraphs a. and b. shall be bypassed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1300.112(10).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 39:

Family Impact Statement

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that this proposed Rule will have no impact on family functioning, stability, or autonomy as described in R.S. 49:972.

Poverty Impact Statement

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the poverty impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on child, individual, or family poverty in relation to individual or community asset development as described in R.S. 49:973.

Public Comments

Interested persons may submit written comments to Robert Starszak, Public Health Epidemiologist, Department of Health and Hospitals, Office of the Secretary, P.O. Box 3013, Baton Rouge, LA 70821-3013. He is responsible for responding to inquiries regarding this proposed Rule.

Public Hearing

A public hearing on this proposed Rule is scheduled for Tuesday, October 29, 2013 at 9:00 a.m. in Room 118, Bienville Building, 628 North Fourth Street, Baton Rouge, LA. At that time, all interested persons will be afforded an opportunity to submit data, views, or arguments either orally or in writing. The deadline for receipt of all written comments is 4:30 p.m. on the next business day following the public hearing.

Kathy H. Kliebert
Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Health Care Data Reporting

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

The proposed rule repeals LAC 48:V. Chapter 151 governing State Center for Health Statistics in its entirety and amends LAC 48:I, Subpart 5 governing Health Planning to add Chapter 131, entitled Health Care Data Reporting. This rule provides for the reporting of health care data (inpatient, emergency department, and ambulatory surgery) by licensed hospitals and ambulatory surgical centers (ASCs) in the state to the Department of Health and Hospitals (DHH) as required by Act 537 of 2008. It is anticipated that the implementation of this proposed rule will have no programmatic fiscal impact to the state other than the cost of promulgation for FY 2013-2014. It is anticipated that $1,148 (SGF) will be expended in FY

2013-2014 for the state's administrative expense for promulgation of this proposed rule and the final rule.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

It is anticipated that the implementation of this proposed rule will not affect revenue collections of state or local governments.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

Licensed hospitals and ASCs in Louisiana may incur additional costs related to additional personnel, software acquisition, and/or software-vendor contracts, which DHH is unable to determine for each facility.

The healthcare data DHH will collect, analyze, and disseminate as per the proposed rule will assist Louisiana's health care consumers in making informed choices about their health care options as these relate to specific treatments and procedures, cost-efficiency, and quality, among other factors of interest.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

It is anticipated that the implementation of this rule will have no effect on competition and employment.

Jerry Phillips
Undersecretary
1309#051

Evan Brasseaux
Staff Director
Legislative Fiscal Office

NOTICE OF INTENT

Department of Insurance
Office of the Commissioner

Companies in Hazardous Financial Condition
(LAC 37:XIII.Chapter 13)

Under the authority of the Louisiana Insurance Code, R.S. 22:1 et seq., and in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq., R.S. 22:11, and R.S. 22:2001 et seq., notice is hereby given that the Department of Insurance proposes to amend Regulation 43. The purpose of the amendment it to update the current provisions of Regulation 43 to maintain consistency with the National Association of Insurance Commissioner's (NAIC) model regulation regarding the standards which the Commissioner may use for identifying insurers found to be in such condition as to render the continuance of their business hazardous to their policyholders, creditors, or the general public.

Title 37
INSURANCE
Part XIII. Regulations

Chapter 13. Regulation 43—Companies in Hazardous Financial Condition

§1301. Purpose

A. The purpose of Regulation 43 is to set forth the standards which the Commissioner of Insurance ("Commissioner") may use for identifying insurers found to be in such condition as to render the continuance of their business hazardous to their policyholders, creditors, or the general public.

B. Regulation 43 shall not be interpreted to limit the powers granted the commissioner by any laws or parts of laws of this state, nor shall Regulation 43 be interpreted to supersede any laws or parts of laws of this state.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11 and 22:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 18:1408 (December 1992), amended LR 39:

§1303. Definitions

A. As used in Regulation 43, the following terms shall have the respective meaning hereinafter set forth:

Control—as defined in R.S. 22:691.2(3)

Person—as defined in R.S. 22:691.2(7)

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11 and 22:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 18:1408 (December 1992), amended LR 39:

§1305. Standards

A. The following standards, either singly or a combination of two or more, may be considered by the commissioner to determine whether the continued operation of any insurer transacting an insurance business in this state might be deemed to be hazardous to their policyholders, creditors, or the general public. The commissioner may consider:

1. adverse findings reported in financial condition and market conduct examination reports, audit reports, and actuarial opinions, reports or summaries;

2. the National Association of Insurance Commissioners Insurance Regulatory Information System and its other financial analysis solvency tools and reports;

3. ...

4. the ability of an assuming reinsurer to perform and whether the insurer's reinsurance program provides sufficient protection for the insurer's remaining surplus after taking into account the insurer's cash flow and the classes of business written as well as the financial condition of the assuming reinsurer;

5. whether the insurer's operating loss in the last twelve-month period or any shorter period of time, including but not limited to net capital gain or loss, change in non-admitted assets, and cash dividends paid to shareholders, is greater than 50 percent of the insurer's remaining surplus as regards policyholders in excess of the minimum required;

6. whether the insurer's operating loss in the last 12-month period or any shorter period of time, excluding net capital gains, is greater than 20 percent of the insurer's remaining surplus as regards policyholders in excess of the minimum required;

7. whether a reinsurer, obligor or any entity within the insurer's insurance holding company system, is insolvent, threatened with insolvency or delinquent in payment of its monetary or other obligations, and which in the opinion of the commissioner may affect the solvency of the insurer;

8. contingent liabilities, pledges or guaranties which either individually or collectively involve a total amount which in the opinion of the commissioner may affect the solvency of the insurer;

9. whether any "person" in "control" of an insurer is delinquent in the transmitting to, or payment of, net premiums to the insurer;

10. - 14. ...

15. whether management has established reserves that do not comply with minimum standards established by state